

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CASE NO. 4:24-CR-00010 RLW/SPM

UNITED STATES OF AMERICA

vs.

MOHD AZFAR MALIK, M.D.

/

MOTION TO DISMISS THE DRUG TRAFFICKING COUNTS

Mohd Azfar Malik, M.D., through undersigned counsel, and pursuant to Federal Rule 12(b)(6), moves to dismiss Counts 1, 3–14, and 22, of the Indictment for failure to state a claim. Those counts, which charge serious drug trafficking offenses, fail to allege a required element: that Dr. Malik prescribed a controlled substance knowing that it was for no medical purpose. Instead, those counts assert only that Dr. Malik ran afoul of regulations (like storing medicine on the wrong floor of his medical office). But as we explain below, noncompliance with a regulation is not sufficient to satisfy the very high burden for hauling a doctor into federal criminal court as a drug trafficker. (Through a separate motion to dismiss, we demonstrate that none of the regulations were violated.)

Introduction

Section 841 and the related charges in the Indictment criminalize drug trafficking. When used to prosecute a doctor, the Government must allege and prove that the doctor prescribed the controlled substance for no medical purpose and *knowing* that it was not for a medical purpose. In other words, the Government must

allege that the doctor was intentionally acting as a drug dealer for his patient, and not as the patient's doctor.

No such allegation exists here. There is no suggestion that a single patient was prescribed a drug he or she did not need. The Government has not alleged that Dr. Malik prescribed the controlled substances knowing there was no medical purpose. Nor could it for there *was* a legitimate and appropriate medical purpose for every single administration of these drugs. Dr. Malik properly prescribed ketamine and esketamine solely to help his patients combat their treatment-resistant depression.

In lieu of alleging that Dr. Malik prescribed these controlled substances for no medical purpose and knowing there was no medical purpose, which the law requires, the Government instead alleges only that the manner in which these ketamine infusions and esketamine nasal spray treatments were administered violated medical procedural regulations. For example, the Government alleges that the treatments were administered in suite numbers different than the suite number on the DEA registration (though in the same building); or that Dr. Malik did not properly supervise the infusions or nasal sprays as they were administered by another doctor in his office. But even assuming for the purpose of this motion that Dr. Malik violated those regulations, there is no crime alleged in the Indictment because the Government has not alleged that the ketamine and esketamine were knowingly prescribed without legitimate medical purpose. Because the Indictment alleges no such thing, and only alleges regulatory violations regarding the administration of

ketamine and esketamine prescribed for a legitimate medical purpose, counts 1, 3–14, and 22 must be dismissed.

Statement of Relevant Facts

Dr. Malik is a 70-year-old board-certified psychiatrist, recognized as a Distinguished Life Fellow of the American Psychiatric Association, who spent the last 40 years building a deserving reputation as an eminent figure in the St. Louis medical community. He completed his psychiatry residency training at St. Louis University Medical Center in 1986 and served as Chief Resident of the Medical Center from 1985–1986.

Over more than four decades, Dr. Malik built a stellar reputation in the community. He has been the Chief Medical Officer of two major behavioral health systems. He was an Adjunct Associate Clinical Professor in the Department of Psychiatry at St. Louis University. He is on the editorial board of *Current Psychiatry*. The St. Louis Chapter of the National Alliance on Mental Illness awarded Dr. Malik with the Exemplary Psychiatrist Award and its prestigious Mortimer Goodman Award, awarded annually to a mental health professional who has made an outstanding contribution to the field, for his service in promoting behavior mental health in the St. Louis region. In 2006, he received the esteemed Missourian Award from the Governor of Missouri. During 2021, Dr. Malik was the President of Missouri Psychiatric Association. It goes without saying that he has never been charged with a crime until this Indictment has, rather absurdly, branded him a drug trafficker.

In 2018, Dr. Malik created COPE, a clinic offering two types of ketamine treatments for patients with treatment-resistant mental illness: ketamine infusions, given intravenously on-site and esketamine (known as Spravato), also given on-site as a nasal spray. Both ketamine and esketamine are groundbreaking options for treatment-resistant mental health that offer the possibility of rapid symptom improvement. Ketamine is classified as a Schedule III controlled substance, defined by DEA as drugs with moderate to low potential for physical and psychological dependence. The Indictment does not allege that any patient abused the ketamine or esketamine, or sought it out for anything other than legitimate treatment. Unlike pill-mill cases, these were real patients, who needed and benefited from the treatment.

In December of 2020, Dr. Asim Ali, an internal medicine physician licensed to practice in Missouri, began assisting Dr. Malik with the ketamine infusions and Spravato treatments. At the time Dr. Ali began working for Dr. Malik, Dr. Ali was under Indictment for charges unrelated to the instant Indictment. *See United States v. Ali, 4:20-CR-00098-HEA.* Nevertheless, given Dr. Ali's valid medical license, Dr. Malik allowed him to assist at the office. While all of the ketamine and Spravato treatments prescribed by Dr. Malik were necessary to treat patients with treatment-resistant depression, the Government now alleges that the doctors acted as drug dealers engaging in a drug trafficking conspiracy because they supposedly violated medical regulations. But noncompliance with a regulation does not make one a drug trafficker, requiring dismissal of the drug trafficking counts in the Indictment.

Procedural History and the Indictment

On January 10, 2024, a grand jury in the Eastern District of Missouri returned an Indictment charging Dr. Malik, along with Dr. Asim Ali, with criminal charges related to Dr. Malik's medical practice and his prescribing of controlled substances. Indictment, ECF No. 2. On January 16, 2024, Dr. Malik pleaded not guilty and the Court entered an order releasing Dr. Malik on bond. As related to this motion, the Indictment charges:

Count 1: Conspiracy to Illegally Distribute Controlled Substances and to Maintain a Drug-Involved Premises in Violation of 21 U.S.C. § 846

Count 1 alleges that Dr. Malik and his co-defendant, Dr. Ali, were in a "drug trafficking conspiracy," Indictment at ¶34, because they did not comply with certain medical regulations. Specifically, Count 1 alleges that Dr. Malik did not properly supervise Dr. Ali when Dr. Ali either infused patients with ketamine or administered Spravato (nasal esketamine), Indictment at ¶41-46, and that this occurred in Suite 220 of Dr. Malik's building even though his DEA registration was for Suite 350, Indictment at ¶9-10, 47. Count 1 does not allege that Dr. Malik knowingly distributed ketamine or esketamine without a legitimate medical purpose.

Counts 3–14: Illegal Distribution of a Controlled Substance in Violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2

Counts 3–14 are substantive § 841(a)(1) (drug trafficking) counts. Each count represents a particular patient and a date of administration of either a ketamine infusion or a Spravato treatment. The "illegal" distribution allegations are only that Dr. Ali "administered the substance indicated outside of the presence of and without

the direct supervision of Dr. Malik,” *not* that Dr. Malik ordered the infusion or nasal spray for no medical purpose or that the patients were drug addicts or were selling the ketamine, or that they were abusing the ketamine in any way. Indictment at ¶59. Simply put, there is no allegation that the controlled substances were prescribed for anything other than a legitimate medical purpose.

Count 22: Maintaining a Drug-Involved Premises in Violation of 21 U.S.C. § 856(a)(2) and 18 U.S.C. §2

Count 22 charges Dr. Malik with managing and controlling a drug premises at Suite 220 of his building because he did not directly supervise Dr. Ali and, rather unbelievably, because Suite 220 was not the suite number on his DEA Registration. Instead, that registration listed Suite 350. Again, the Indictment does not allege the required element to show that this medical doctor was maintaining an illegal drug premises: that he was distributing controlled substances for no legitimate medical purpose.

LEGAL MEMORANDUM AND ARGUMENT IN SUPPORT OF DISMISSAL

I. The Indictment Fails to State a Claim Because the Government Does Not Allege that Dr. Malik Prescribed a Controlled Substance Knowing it was For No Medical Purpose.

a. In a prosecution charging a doctor under 21 U.S.C. §§ 841, 846, and 856 the Indictment must allege that the doctor prescribed the controlled substance knowing it was for no medical purpose.

In an egregious misuse of their charging authority, the government has charged Dr. Malik with drug trafficking offenses even though the allegations in the Indictment, even if accepted as true, do not support such charges. Title 21 U.S.C. § 841, makes it a federal crime, “[e]xcept as authorized[,] ... for any person knowingly

or intentionally ... to manufacture, distribute, or dispense ... a controlled substance.” 21 U.S.C. § 841(a). There is a well-settled exception for doctors under these drug trafficking statutes because doctors are permitted by federal regulation to prescribe and distribute controlled substances. 21 C.F.R. § 1306.04. This regulation authorizes registered doctors to dispense controlled substances via prescription if the prescription is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). A prescription is “authorized,” and therefore lawful, if it satisfies this standard. *Ruan v. United States*, 597 U.S. 450, 455 (2022).

Because doctors can lawfully distribute and dispense controlled substances, when prosecuting a doctor under § 841 and the other drug trafficking statutes,¹ the Government must allege and prove that the doctor was acting outside the bounds of professional medical practice. Regarding the elements of § 841, the Judicial Committee on Model Jury Instructions for the Eighth Circuit explained that “[w]hen a physician is charged, special considerations apply,” directing courts to the standard that physicians are authorized to dispense controlled substances when the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Eighth Circuit Manuel of Model Jury

¹ The other drug trafficking statutes charged, 21 U.S.C. § 846 and § 856, similarly exempt those who are authorized to distribute controlled substances, like doctors, from criminality. See, e.g., *United States v. Smithers*, 92 F.4th 237 (4th Cir. 2024) (vacating convictions under § 841 and § 856 where the jury was not instructed that the Government must prove a defendant maintained premises for the purpose of distributing a controlled substance *without a legitimate medical purpose*).

Instructions for the District Courts of the Eighth Circuit, 2023 Edition. The Committee noted that the *Ruan* Court expressly held that the Government must prove that a defendant knowingly and intentionally acted in an unauthorized manner – that is, without legitimate medical purpose. *Id.* The government must show that the doctor’s authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, such as the personal profit of the physician. *See id.; United States v. Hung Thien Ly*, 543 F. App’x 944 (11th Cir. 2013) (“To convict a licensed physician under § 841(a)(1), the Government must prove that the physician dispensed controlled substances outside of the usual course of professional practice and not for a legitimate medical purpose, and that he did so knowingly and intentionally.”). A physician is only criminally liable when he ceases to distribute or dispense controlled substances as a medical professional and acts instead as a “pusher.” *United States v. Feingold*, 454 F.3d 1001, 1003 (9th Cir. 2006), quoting *United States v. Moore*, 423 U.S. 122, 138, 143 (1975).

In *Ruan*, the Supreme Court made clear in a unanimous opinion that the Government must not only prove that a doctor was dispensing the controlled substances without a legitimate medical purpose and beyond the bounds of medical practice, but also that the doctor *subjectively* did so with bad intent.² Our Indictment

² While *Ruan* codified this standard, courts have long acknowledged the “special considerations” that apply when a doctor is charged with drug trafficking. *See United States v. Katz*, 445 F.3d 1023, 1028 (8th Cir. 2006) (doctor becomes a criminal only

does not even allege that the prescriptions themselves were done with no legitimate medical purpose, let alone that Dr. Malik subjectively believed that his patients did not need the treatment. *See also United States v. Smithers*, 92 F.4th 237 (4th Cir. 2024) (reversing over 800 counts of conviction under § 841 where the Court did not instruct the jury that the Government must prove a defendant subjectively believed that he was distributing without a legitimate medical purpose after *Ruan*).

Therefore, once the Government chooses to charge a doctor who is registered to dispense a controlled substance with drug trafficking or maintaining a drug premises, the Government must allege that the doctor prescribed the controlled substance knowing there was no medical purpose. To allow otherwise would be to permit the Government to criminally indict a doctor for technical violations of regulations even where the doctor was treating his patients in good faith.³ But

when he issues prescriptions “for the purpose of assisting another in the maintenance of a drug habit or ... for other than a legitimate medical purpose, i.e. the personal profit of the physician”), quoting *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994); *United States v. Smith*, 573 F.3d 639 (8th Cir. 2009) (same); *United States v. Stump*, 735 F.2d 273, 276 (7th Cir. 1984) (holding that to support a conviction the government must show doctor’s pattern of prescribing drugs “could not possibly be consistent with legitimate medical treatment”); *United States v. Bartee*, 479 F.2d 484, 489 (10th Cir. 1973) (standard for a doctor was a showing that the prescription was not “for a legitimate medical purpose”).

³ The logical consequences of permitting the Government to criminally indict a doctor acting in good faith for technical violations of regulations demonstrate the absurdity of the Government’s position. For example, under the Government’s theory, a doctor who keeps a controlled substance locked in a safe inside of an office could be indicted as a drug trafficker for violating 21 C.F.R. § 13.01.75(b), which requires that controlled substances to be stored “in a security locked, substantially constructed cabinet” (emphasis added). A doctor who uses the wrong symbol (for example, using “C2” instead of “C-II” to denote a schedule II substance) could be indicted as a drug trafficker for violating 21 C.F.R. § 1302.04, which requires specific symbols to be used

violating a medical regulation is not enough: “A practitioner becomes a criminal ... when he ceases to be a physician *at all.*” *Feingold*, 454 F.3d at 1011.⁴

Following *Ruan*, courts around the country are reversing convictions, ordering new trials, and holding that juries must be properly instructed on the *Ruan* requirement – that is, they must be instructed that the charged doctor must subjectively believe he is prescribing the medication without a legitimate medical purpose. *See, e.g., Smithers*, 92 F.4th 237 (finding plain error with jury instructions that did not require jurors to find that doctor subjectively acted as a drug dealer and not as a doctor); *United States v. Duldulao*, No. 20-13973 (11th Cir. Nov. 29, 2023) (vacating § 841 convictions after finding plain error in jury instructions that did not include the *Ruan* requirement); *United States v. Otuonye*, 18-CR-10085-EFM (D. Kan. July 11, 2023) (granting a defendant pharmacist’s motion to vacate § 841 convictions under 28 U.S.C. § 2255 where defense counsel failed to object to jury instructions that did not encompass the *Ruan* requirement); *United States v. Murphy*, 5:20-CR-291-LSC (N.D. Ala. Feb. 17, 2023) (vacating the § 841 conviction of a doctor following *Ruan*).

on the labeling of a controlled substance. These outcomes cannot be what Congress intended when it outlawed drug trafficking.

⁴ This is not to say that a doctor who violates medical regulations will not face consequences. Both the federal and state licensing boards can take action. And the federal government could even charge 21 U.S.C. § 842, which addresses a whole host of regulatory offenses. Instead of the severe penalties for drug trafficking in § 841 of up to 20 years in prison, however, § 842 makes such regulatory violations appropriately subject to “civil penalties.”

- b. The Indictment fails to allege that Dr. Malik prescribed the controlled substances knowing they were for no medical purpose because Dr. Malik prescribed ketamine and esketamine exclusively for legitimate medical purposes.

Although the Government alleges in its Indictment that Dr. Malik is a licensed medical doctor authorized to prescribe controlled substances, the Government fails to allege, nor could it, that Dr. Malik prescribed ketamine and esketamine knowing it was for no medical purpose. Therefore, as alleged by the Government, the Indictment fails to state a claim.

Dr. Malik's case fits squarely into the concern addressed by the *Ruan* Court – that is, absent an allegation that Dr. Malik prescribed the medication knowing it was for no medical purpose, the Indictment fails to distinguish between the wrongfulness proscribed by statute and the innocent conduct of a licensed medical doctor. As the *Ruan* Court noted, “in § 841 prosecutions, a lack of authorization is often what separates wrongfulness from innocence.” *Id.* at 458. Here, the Indictment fails to allege a crime because it does not (and cannot) allege that Dr. Malik prescribed the medications knowing they were for no medical purpose. In fact, the Indictment appears to concede that Dr. Malik subjectively believed that his patients needed the ketamine and esketamine for their treatment-resistant depression.⁵ Unlike other cases in which a doctor is charged with drug trafficking, there is no allegation here

⁵ Notably, only after the defense made a specific *Brady* request, the Government provided statements from patients named in the Indictment that further support the point that Dr. Malik believed his patients needed the controlled substance for a legitimate medical purpose. We detail some of these facts in a separate motion to compel.

that the patients were addicts, that they were abusing the drugs, or that they sold the drugs. To the contrary, every single administration of ketamine and Spravato were done in Dr. Malik's office where there was no chance of abuse.

The Government acknowledges, and the Grand Jury correctly found, that Dr. Malik is licensed to practice medicine and authorized to dispense controlled substances. The Indictment includes that Dr. Malik "was a psychiatrist, licensed to practice medicine in the state of Missouri." Indictment at ¶ 1; and, "[a]t all relevant times, Dr. Malik had two DEA registrations, which authorized him to dispense controlled substances in schedules II through V..." *Id.* at ¶ 8. These dispensations, then, are not "inherently illegitimate; we expect, and indeed want, doctors to prescribe the medications that their patients need." *Ruan* at 459. In § 841 prosecutions, then, "it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself." *Id.* "[A]uthorization plays a 'crucial' role in separating innocent conduct – and, in the case of doctors, socially beneficial conduct – from wrongful conduct." *Id.* citing *United States v. X-Citement Video*, 513 U.S. 64, 72–73 (1994). Here, Dr. Malik's conduct was innocent: he prescribed ketamine and esketamine for the sole purpose of helping his patients who suffered from treatment-resistant depression.

Unlike the Indictment here, which does not allege that Dr. Malik (or even Dr. Ali) prescribed the ketamine for no legitimate purpose, Indictments of doctors in the Eighth Circuit and around the country require egregious facts demonstrating that the doctor has crossed the line to drug dealer. Take, for example, *United States v.*

Smith, 573 F.3d 639 (8th Cir. 2009). Even though *Smith* is pre-*Ruan* and erroneously found that only an objective standard was necessary to convict a doctor, the facts are typical of what is required to charge a doctor. In *Smith*, the doctor assisted drug addicts “in the maintenance of [their] drug habit[s]” by approving thousands of opioid prescriptions a day over an online website, totaling 72,000 orders in about a year for \$3.50 a prescription. In our Indictment, the Government does not allege comparable facts because those facts do not exist in this case.⁶

The *Ruan* Court made clear that using regulatory violations to determine whether a prescription is for a medical purpose, as the Government attempts to do here, is insufficient. *Ruan* at 459. The Government accuses Dr. Malik of regulatory violations – for example, dispensing ketamine in a suite one floor below the DEA

⁶ We could list many cases where the doctors are alleged to be drug dealers and the patients are alleged to be addicts, which is nothing like what is alleged here. See, e.g., *United States v. Elder*, 682 F.3d 1065 (8th Cir. 2012) (doctor had no patient-doctor relationship, did not see patients or keep patient records when authorizing prescription refills, repeatedly prescribed a highly unusual combination of drugs, and at least two patients died before the dates on their prescriptions); *United States v. Katz*, 445 F.3d 1023 (8th Cir. 2006) (doctor did not accept appointments, lived at his office, charged a flat fee, and prescribed medication to patients upon request, requiring no medical documentation at their initial visit); *United States v. Rosen*, 582 F.2d 1032, 1035–36 (5th Cir. 1978) (identifying prescribing practices as probative of illicit distribution by a physician: (1) prescribing an inordinately large quantity of controlled substances, (2) issuing large numbers of prescriptions, (3) not giving physical examinations, (4) warning patients to fill prescriptions at different drug stores, (5) issuing prescriptions to a patient known to be delivering the drugs to others, (6) prescribing controlled drugs at intervals inconsistent with legitimate medical treatment, (7) using street slang rather than medical terminology for the drugs prescribed, (8) the absence of a logical relationship between the drugs prescribed and treatment of the condition allegedly existing, and (9) writing more than one prescription on a single occasion in order to spread them out).

registration's address; or failing to properly supervise Dr. Ali in the administration of ketamine. Indictment at ¶¶ 39–40, 41–42. These accusations, even if true,⁷ do not come close to rising to the level of alleged drug trafficking offenses because the Government has not alleged that the prescriptions were not for a legitimate medical purpose. Without that allegation, the Indictment has not stated a federal drug trafficking claim.

* * *

The Government's prosecution of Dr. Malik exemplifies the overcriminalization of well-meaning doctors whose singular goal is to help their patients. The drug trafficking statute at issue here is meant to criminalize the illegal and harmful trade of controlled substances – not to penalize doctors for treating their patients with much-needed prescription medication. Overcriminalization places a burden on the administration of justice, resulting in wildly improper convictions for conduct that falls outside the constitutionally anticipated federal purview.

Our drug trafficking statutes simply do not encompass Dr. Malik's conduct. But while the Supreme Court repeatedly tells prosecutors that they have gone too

⁷ Dr. Malik does not concede he violated any regulations, as he argues in his separate motion to dismiss. However, for purposes of this motion, whether Dr. Malik violated the regulations or not is of no consequence because violations of the regulations cannot be used to allege Dr. Malik prescribed the medications knowing there was no medical purpose.

far, they continue to push the bounds of our federal criminal code in ways not contemplated by the legislature.⁸

Counts 1 and 3–14 of the Indictment carry penalties of up to 10 years in prison and Count 22 carries a 20-year maximum sentence, reflecting the seriousness of true drug trafficking offenses. Congress did not intend for a licensed physician prescribing schedule III-controlled substances to patients for legitimate medical purposes in good faith to face 150 years in prison. Dr. Malik, a well-respected 70-year-old doctor who has served this community for the past 40 years does not deserve a federal criminal Indictment based on a massive overreach of the federal criminal statutes to cover technical violations of regulations.

Dr. Malik is not a drug trafficker. The Court should dismiss the drug trafficking counts and not force Dr. Malik to fight this case before a jury.

⁸ The Supreme Court’s decision is *Ruan*, which was 9-0, is a prime example of the Supreme Court *unanimously* overturning trial and appellate courts’ expansive reading of the criminal code. *Ciminelli v. United States*, – U.S. – (2023) (unanimously reversing conviction “despite [the prosecution] indicting, obtaining convictions, and prevailing on appeal based solely on [a theory not covered by the statute]”); *McDonnell v. United States*, 579 U.S. 550 (2016) (9-0: reversing conviction because of “the broader legal implications of the Government’s boundless interpretation of the ... statute”); *Kelly v. United States*, 590 U.S. – (2020) (9-0: “The evidence the jury heard no doubt shows wrongdoing – deception, corruption, abuse of power. But the federal fraud statutes at issue do not criminalize all such conduct”); *Cleveland v. United States*, 531 U.S. 12 (2000) (9-0: “We resist the Government’s reading of [the statute] as well because it invites us to approve a sweeping expansion of federal criminal jurisdiction in the absence of a clear statement by Congress”); *see also Yates v. United States*, 574 U.S. 528, 536 (2015) (rejecting the Government’s “unrestrained reading” of a statute, which “extend[ed] beyond the principal evil motivating its passage”); *Van Buren v. United States*, 593 U.S. – (2021) (rejecting “Government’s interpretation of the statute” because it would attach criminal penalties to a breathtaking amount of commonplace ... activity”).

Respectfully submitted,

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